**RZ 765/96**

**VETERINARY PRODUCT – MERCOSUR (Southern Common Market) – ESTABLISHMENT – VALIDATION**

It adopts and brings into force the health rules for the Supplementary Regulation of the Regulatory Framework of Veterinary Products for Establishments, Veterinary Products and Technical Responsibility. Such regulation was approved by Common Market Group Resolution No. 39/96.

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EX-SENASA RESOLUTION No.765/96

BUENOS AIRES, December 3, 1996

HAVING REGARD TO docket file No. 44316/96 in which the Coordination Office for International Relations of this area proposes that rules complying with COMMON MARKET GROUP (MERCOSUR) resolution be adopted, and

WHEREAS:
For the purpose of complying with what was provided for in the Asunción Treaty, the Member States have ordered that health rules for the Supplementary Regulation of the Regulatory Framework of Veterinary Products for Establishments, Veterinary Products and Technical Responsibility and the Regulation of the Validation System for Veterinary Products be adopted.
In compliance with such decision, the COMMON MARKET GROUP in its capacity as executive body of the SOUTHERN COMMON MARKET has entered Resolutions Nos. 39/96 and 40/96.
The adoption of those resolutions within the national legislation is appropriate.
The SUB-DIRECTORATE FOR LEGAL AFFAIRS has issued its legal opinion on this matter.
The undersigned has jurisdiction to hear in this instance pursuant to sections 9 and 33, Annex I of Decree No. 1553, dated August 12, 1991 which regulates Act No. 23899.

Therefore,
THE GENERAL SUB-MANAGER
P/P OF THE NATIONAL SERVICE FOR ANIMAL HEALTH
RESOLVES:

SECTION 1.- The health rules for the Supplementary Regulation of the Regulatory Framework of Veterinary Products for Establishments, Veterinary Products and Technical Responsibility, approved by COMMON MARKET GROUP Resolution No. 39/96 are adopted and brought into force.

SECTION 2.- The Regulation of the Validation System for Veterinary Products, approved by COMMON MARKET GROUP Resolution No. 40/96 is adopted and brought into force.

SECTION 3.- This Resolution shall enter into force as from the date of its publication.

SECTION 4.- Have it notified, published, transferred to the National Directorate for Official Registry and filed.

Signed: Jorge P. CHVIDIA (Sub-Manager)

RESOLUTION No. 765/96

MERCOSUR/GMC/RESOLUTION No. 39/96

SUPPLEMENTARY REGULATION OF THE REGULATORY FRAMEWORK OF VETERINARY PRODUCTS

HAVING REGARD TO: Asunción Treaty, Protocol of Ouro Preto, Resolutions Nos. 1/93 and 91/93 of the Common Market Group and Recommendation No. 16/96 of SGT No. 3 “Technical Regulations.”

WHEREAS:

The need to harmonize the content of the document about the Regulatory Framework of Veterinary Products

THE COMMON MARKET GROUP
RESOLVES:

Sect. 1.- The “Supplementary Regulation of the Regulatory Framework of Veterinary Products” for Establishments, Veterinary Products and Technical Responsibility, which is attached hereto as Annex I, is hereby approved.

Sect. 2.- The Member States shall bring into force the legislative, regulatory, and administrative provisions necessary for complying with this Resolution by means of the following bodies:

Argentina
NATIONAL SERVICE FOR ANIMAL HEALTH, SECRETARIAT OF AGRICULTURE, FISHERIES AND FOOD
Brazil
MINISTRY OF AGRICULTURE AND SUPPLY
Paraguay
MINISTRY OF AGRICULTURE AND LIVESTOCK
Uruguay
MINISTRY OF LIVESTOCK, AGRICULTURE AND FISHERIES
DIRECTORATE GENERAL FOR LIVESTOCK SERVICES
DIRECTORATE FOR VETERINARY LABORATORIES “MIGUEL C. RUBINO” (DILAVE.)

Sect. 3.- This Resolution shall enter into force in MERCOSUR on October 1, 1996.

XXII GMC – Buenos Aires, VI/21/1996

ANNEX I

SUPPLEMENTARY REGULATION OF THE REGULATORY FRAMEWORK FOR VETERINARY PRODUCTS

CHAPTER I

On the establishments of Veterinary Products

Section 1

Any establishment that manufactures, handles, fractionates, markets, stores, imports, or exports Veterinary Products for itself or for third parties shall be registered with the Competent Official Body of its Country.

Section 2

The establishment registration mentioned in section 1 hereof shall be requested to the Competent Official Body of the Country, by the Owning Company or its legal representative by means of an Application where the following shall appear:

I.- Authenticated copy of the Company Name and verification of its legal incorporation.
II.- Full address of the Company.
III.- Legal Representation and verification of such representation.
IV.- Activities of the establishment,
V. Type(s) of product(s)
VI. Name, profession, and registration number of the technician in charge.
VII. Statutory provisions on which the Application for Establishment Registration is based.

Section 3

The Application for Registration of Establishments that manufacture or fractionate Veterinary Products shall be accompanied by a descriptive report of the facilities and specific equipment for the activity or activities to be developed and layout plans following these directions:

I.- General transversal and longitudinal drawing to a minimum scale of 1:200.

II.- Drawing to scale 1:50 for drain system.

III.- Description of the control system to prevent environmental pollution and risks for health in compliance with the following:

a.- Safety rules to prevent environmental pollution caused by production and storage of products.
b.- Safety rules to prevent environmental pollution caused by the handling of biological products.

Section 4

The Competent Body shall be given sufficient prior notice of any plant relocation, modification or expansion for the purpose of carrying out inspections for authorization and granting the relevant authorizations.

The period for the Competent Body to grant the authorization or for the modifications that may be made shall not be longer than 60 days as from the time the inspection for authorization was requested. Should refurbishment and/or modification concern any of the manufacturing areas, the Competent Body shall decide whether the tasks developed by such area are to continue or not.

Section 5

Should the Company ownership be transferred or its name be changed, the Registering Competent Body shall be notified of that within a period of not more than 7 days as from the date the change is made for the purposes of authentication.

ON THE FACILITIES:

Section 6

The Establishments referred to in section 1 hereof, except for those which exclusively market, store, import, or export, shall be supplied with facilities and equipment suitable for complying with production, quality control, hygiene and work safety, health and environmental protection rules. In addition, the following requirements shall be met:

I.- They shall be provided with an area exclusively devoted to handling or manufacturing veterinary products, the facilities of which shall satisfy the production volumes and capacities stated.

II.- The industrial facilities shall be detached from buildings intended for housing or other unrelated constructions.

III.- The design and materials used to build the floors, walls, and roofs of the premises where Veterinary Products are handled, manufactured or stored shall ensure that conditions suitable for cleaning and disinfection exist.

IV.- They shall be supplied with the equipment, tools and conditions necessary for the intended purpose.

V.- They shall be provided with areas suitably detached and intended for storing:
a.- raw materials, packaging and conditioning materials (with a detached quarantine area.)
b.- finished products (with a detached quarantine area.)
c.- products rejected, returned, withdrawn from the market and for rebuttal.

VI.- The above-mentioned warehouse areas shall meet the requirements suitable for storage.

VII.- They shall be supplied with the following auxiliary areas:
a.- Staff resting room and canteen, detached from the other areas, when the corresponding legislation so requires.
b.- Changing rooms and restrooms easy to access and suitable for the number of users. Restrooms shall not be directly attached to the production and storage areas.
c.- Maintenance area, detached from the other areas.

Section 7

When laboratories, where raw material and finished product quality controls are carried out, are located at the Establishment, they shall be detached from the production area.

Section 8

The Establishment managers shall arrange for adequate and continuing training of every Veterinary Product handler in hygienic handling of such products and in personal hygiene.

Section 9

Establishments shall be equipped with means capable of eliminating or reducing the risk of pollution arising from industrialization processes, which may cause harmful effects on health and the environment.

Section 10

The establishments manufacturing or handling pharmaceuticals to be taken by injection or others which require aseptic conditions of preparation shall have an area especially devoted to such end and shall meet the following requirements:

I.- The above-mentioned area shall be detached and the condition of its floor, walls, ceiling, doors and windows shall be suitable for their hygiene, cleaning and disinfection. Furthermore, the area shall be supplied with an air exchange system ensuring the lack of pollution in the finished product.

II.- The buildings and facilities shall be designed in such a way that projections such as columns, equipment and furniture are reduced to a minimum. Pipes and ducts shall be so installed as to make cleaning easy. At manufacturing and fractionating areas, the presence of basins and waste drain pipes shall be avoided.

III.- The areas where products are handled shall be supplied with tables covered with waterproof material, instruments and tools necessary for the practices performed in such areas.

IV.- Changing rooms shall be closed chambers with a system ensuring that air is appropriately supplied. Movement across these rooms shall take place in such a way that the various stages of change from dirty into clean clothes are totally separate. The equipment and materials for cleaning hands shall be located inside the changing rooms.

V.- The chamber doors between rooms shall not be opened at the same time, for which there shall be systems of security locks and visual and/or auditory alerts to prevent that from happening.

VI.- At the production and packaging areas, product contamination shall be prevented by appropriately supplying filtered air and pressure gradient or a system having equivalent effect.

VII.- Should they have *vivaria* with animals used for production and/or “in vivo” control, they shall have rules and keep record of environmental, hygiene, cleaning, disinfection and handling conditions.

VIII.- Clothing worn in the production areas shall be clean and meet the requirements ensuring that the finished product is not contaminated. After it has been worn, it shall be cleaned, disinfected, and/or sterilized. All the members of staff that enter the aforementioned production area shall wear these items of clothing and maintain proper personal hygiene.

Section 11

The Establishment manufacturing Biological Products shall be supplied with buildings and facilities built or adapted to fit such purposes, pursuant to the following requirements:

I.- Walls, floors, ceilings, doors, and windows shall be built with waterproof, non-absorbent, washable materials so as to ensure perfect hygiene, cleaning, and disinfection. They shall be smooth, of light colors and have no cracks. Angles between walls, between walls and floors, and between walls and ceilings shall have curved joints and be hermetic to make cleaning easy.

II.- There shall be an abundant supply of pressurized drinking water at a suitable temperature, with an appropriate distribution system and protected against contamination. Effluents and waste water shall be treated before they enter the general network for the purpose of eliminating pathogenic microorganisms and contaminants that pose a risk and arise from the manufacturing processes.

III.- They shall be provided with a safety system specifically planned to prevent the risks of contamination of the environment as well as cross-contamination as a result of the various operational systems between microorganisms which may survive.

IV. The detachment and independence in septic and aseptic areas shall be ensured and their hygiene and cleaning conditions shall be the best. These areas shall be supplied with entry and exit barriers for traffic between them both so that the staff members and equipment entering the aseptic or clean area comply with the hygiene and safety measures recommended. At the same premises, various virulent germs may be handled provided that the safety measures and requirements corresponding to each individual germ are met.

V.- Access to the areas referred to in the previous item shall be through the changing rooms.

VI.- They shall be equipped with cold-storage chambers with accurate thermo-regulators and a paper-based system for recording temperatures. The capacity of said cold-storage chambers shall be sufficient to serve their purpose and their circulation system shall ensure that temperature is uniform for raw materials and products requiring to be stored at low temperature to be preserved.

VII.- They shall be supplied with stove chambers having the same equipment referred to in the previous item.

VIII.- They shall be provided with premises to house the animals that shall be used for production and/or “in vivo” control. They shall have rules and keep record of environmental, hygiene, cleaning, disinfection and handling conditions.

IX.- They shall be supplied with premises for inoculated animals. Such premises shall be completely isolated from the outside and be equipped with its own ventilation system with filtered air inlets and outlets. Animal feces as well as the materials that have been used and the carcasses shall be gathered by means of effective methods of decontamination.

X.- Clothing worn in the production areas shall be clean and meet the requirements ensuring that the finished product is not contaminated. After it has been worn, it shall be cleaned, disinfected, and/or sterilized. All the members of staff that enter the aforementioned production area shall wear these items of clothing and maintain proper personal hygiene.

XI.- Changing rooms shall be closed chambers with a system ensuring that air is appropriately supplied. Movement across these rooms shall take place in such a way that the various stages of change from dirty into clean clothes are totally separate. The equipment and materials for cleaning hands shall be located inside the changing rooms.

XII.- The chamber doors between rooms shall not be opened at the same time, for which there shall be systems of security locks and visual and/or auditory alerts to prevent that from happening.

XIII.- At the production and packaging areas, product contamination shall be prevented by appropriately supplying filtered air and pressure gradient or a system having equivalent effect.

Section 12

Since they are mixed plants devoted to manufacturing Biological Products, Pharmacological Products or Foodstuffs with drugs, detached facilities shall be mandatory for each of such products and foodstuffs to be manufactured.

Section 13

The Establishment that only store, distribute, market, import or export veterinary products shall meet items “a” and “b” of Section 3, and the following requirements:

I.- Premises shall be detached from buildings intended for housing or other unrelated constructions.

II.- Facilities shall be suitable for products to be properly preserved. Rooms shall be dry, ventilated, and built with materials protecting them from incompatible temperatures and ensuring good conditions for cleaning and disinfection.

III.- In case they deal with veterinary products requiring cold storage, they shall be supplied with equipment suitable for such products to be properly preserved.

Section 14

The establishments that do not have adequate facilities for carrying out the quality control of their products and raw materials shall perform these activities at third parties’ laboratories previously authorized for such purpose by the Official Body.

CHAPTER II

ON THE PROFESSIONAL RESPONSIBILITY

Section 15

The establishments carrying out the activities stated in this Regulation are bound to have a Technician in charge. This technical responsibility shall be taken by legally authorized University graduates of the Tertiary level.

I.- The responsibility for a product manufactured at a third parties’ establishment shall be taken by the owner or holder of the registration of such product.

II.- If the production line were of biological nature, a Veterinarian shall be in charge of the Technical Management.

III.- When dealing with pharmacological products, chemicals, or foodstuffs with drugs, a Veterinarian, Chemist, Biochemist, or Pharmacist shall be in charge.

IV.- In case the technical assistance of the establishment is terminated or interrupted, the assistant shall be replaced and the competent Official Body shall be notified. The responsibility of the Technician that leaves both in connection with the establishment and with the products manufactured therein shall be canceled by operation of law. The Technician shall continue to be held responsible for the last batch or series manufactured during his/her time as Technician of the establishment.
a.- The establishment shall not be able to manufacture new batches until a new technician is appointed.
b.- The new technician shall take responsibility once he is authorized by the competent Official Body.

V.- At the establishments where the activities stated in Section 13 hereof are carried out, the technical responsibility shall be held by a Veterinarian.

VI.- The professionals referred to in this section shall submit a copy of their University degree duly authenticated and their professional registration number issued by the relevant authority, and a copy of the agreement between the professional and the firm to the Competent Official Body.

## CHAPTER III

## ON THE VETERINARY PRODUCTS

### Section 16

Any veterinary product shall be registered with the competent official body, pursuant to the relevant registration forms and to the provisions of the Regulatory Framework for Veterinary Products, which are supplemented by the provisions hereof.

## ON THE FORMULATIONS

### Section 17

The complete formula with all its constituents, specified in their technical names, including the amounts stated using the metric system or internationally recognized units, shall be stated in the application for registration of veterinary products. In addition, the following points shall be considered:

I.- Pharmacological products:
a.- Pharmaceutical form of absorption.
b.- Complete formula with all its constituents, specified in their technical names, including the amounts stated using the metric system or internationally recognized units. In addition, whether overages of some constituents are necessary or not shall be stated.
c.- Manufacturing method with operations to be performed.

d.- State the registration of the basic constituents of the formula in the internationally accepted pharmacopoeias, if any.
e.- State the method(s) used for the active principle(s) dosage. In the absence of recognized pharmacopoeias rules, the control processes adopted by the firm in charge shall be described.
f.- Indications for use, specifying the target animal species.
g.- Route and method of administration, indications for use.
h.- Doses and the justification thereof.
i.- Product pharmaco-kinetic, bioavailability, routes of absorption, dissemination and elimination of active substances and/or the metabolites thereof. The product safety, local absorption and efficacy tests shall be carried out in the target species during the stage of product development.
j.- Product pharmaco-dynamics.
l.- Data about side-effects, incompatibilities, pharmacological antagonisms, contraindications, limitations on use, undesirable biological effects.
m.- Data about residues and restrictions on use.
n.- Poisonings, antidotes (if any,) general precautions, preservation and expiration.

II.- Biological products:
a.- Pharmaceutical form of presentation (nature, type of packaging and the content thereof.)
b.- Definition of biological line.
c.- Qualitative and quantitative formula: Biological and chemical composition.
d.- Briefly describe the manufacturing process, origin, characterization, and control test of strain.
e.- Target animal species.
f.- Doses, volume of vaccine dose.
g.- Route and method of administration, indications for use and vaccination program.
h.- Time required to provide immunity and the duration thereof.
i.- Side-effects, incompatibilities, contraindications, and antagonisms.
j.- General precautions, preservation (temperature) and expiration.

Section 18

Any change in the formulation shall only be allowed when previously authorized by the registering official body;

I.- The request for changing active substances shall be accompanied by a new and full application for registration together with its relevant label drafts.

II.- In the event of change of excipients, provided that they do not damage the quality of the finished product, the competent authority shall authorize the change when technically justified without the submission of a new application or changes in the labels.

Section 19

The manufacturing or importing establishments shall not be able to obtain various registrations for veterinary products having identical composition and active substances but different names.

ON THE LABELS

Section 20

The texts of labels and package leaflets shall necessarily include the following:

I.- Name of product.
II.- Formula or composition: description of the composition in active substances of the formula stated quantitatively.
III.- Indications, purposes or uses.
IV.- Contents: the following shall be stated:
a.- Number of unit(s) and/or doses (Tablets, coated tablets, pills, capsules, ampoules and the like) that the commercial packaging contains.
b.- For powders or liquids of any nature, the weight or volume of the product contained in the commercial packaging shall be stated.
c.- For pasty or semi-solid preparations (creams, pastes, ointments and the like) and granulated preparations, the weight of the product contained in the commercial packaging shall be stated.
d.- For medicated bandages, collars, ear-tags or the like, the length, weight, and number of unit(s) contained in the commercial packaging shall be stated.
V.- Dose per animal species, method of administration and indications for use, highlighting the caption: VETERINARY USE.
VI.- Warnings, precautions, contraindications, and antidote if any.
VII.- Packaging requirements (temperature, where appropriate.)
VIII.- Restrictions on use, where appropriate.
IX.- Statement of PRESCRIPTION DRUG, where appropriate.
X.- Registering body, registration number and date.
XI.- Name and address of establishment owning the registration or importing representative.
XII.- Name and professional registration number of the technician in charge.
XIII.- Number of batch/series.
XIV.- Date of manufacture.
XV.- Expiration date.

XVI.- The product formula, composition or active constituents, indications and directions for use or other data required may be excluded from labels when they are stated in the relevant package leaflet.

XVII.- The product name and batch/serial number of ampoules and little containers, packed in isolation or grouped into boxes, shall be stated on them whereas the other data required in this section shall appear on leaflets.

XVIII.- On the labels of diluents of injection products, the registered product, nature, content and trade name shall be specified. On the labels of stabilizers or the like, packed separately, their nature and content shall be specified. They are exempted from stating the registered product trade name.

XIX.- On the labels of aerosols and products holding gas under pressure, the net content and volume of the liquid contained shall be stated when there are no other specific rules.

XX.- The storage requirements (temperature, humidity, light) inherent in each product as well as precautions if any shall be stated in a clear and detailed manner on labels and package leaflets.
XXI.- Labels and package leaflets may be simultaneously printed in Spanish and Portuguese. The font size used shall have the necessary dimensions to be easily read.

ON THE RULES OF QUALITY CONTROL OF VETERINARY PRODUCTS

Section 21

Any veterinary product shall meet the following control requirements:

I.- On raw materials
a.- Physico-chemical and biological characterization of substances accompanied by qualitative tests and quantitative assays.
b.- The establishment shall have files of the analyses carried out, specifying the raw material re-analysis date where appropriate.
c.- The documentation related to a batch quality control shall be kept in a file for a one-year period after such batch period of validity expires or for a five-year period when dealing with raw materials which do not have a period of validity specified.
d.- The raw materials which cannot be analyzed because they are dangerous shall be accompanied by a supplier's certificate of analysis which shall be kept in a file.

II.-Finished pharmacological products
a.- Set the tolerance margins of the formulation basic constituent concentration diversions provided that there are no specifications.
b.- Each batch produced pursuant to the product pharmaceutical form and route of administration shall comply with sterility, safety and pyrogen tests.

III.-Biological products
a.- Any biological product batch shall be subjected to the following controls as the case may be after such batch is manufactured and before it is marketed:

1) sterility
2) purity
3) safety
4) efficacy
5) potency
6) other necessary controls complemented by chemical, physico-chemical, and biological tests (serology and immunogenicity) ensuring the patterns required by the regulations of each product type and feature.

IV.- The quality control laboratory shall keep the quality control specifications and analytical methods used for raw materials, products in progress, finished products, and packaging materials in a file and in writing.

V.- Toxicity control
a.- The manufacturer shall submit the toxicity control data of the active constituents under the stated conditions of use including the following points: carcinogenesis, teratogenesis, mutagenesis, resistance to the pathogens, blood dyscrasia, neurotoxicity, hypersensitivity, effects on regular reproduction and plant life and the like.
b.- To comply with the previous item, accredited bibliography and/or scientific-technical work shall be submitted.

VI.- Stability conditions
Within the quality control requirements, the methods applicable to each product type determining the maintenance of pharmacological and biological features throughout all the period of validity and pursuant to specific rules shall be stated.

VII.- Protocol of production
For each batch produced, a protocol of production with the following data shall be made:
a.- Product name and code.
b.- Protocol controls and tests carried out on raw material. Certificates of analysis of origin shall be accepted when raw materials are used within the period of validity thereof.
c.- Name of the technician in charge.
d.- Date of manufacture of batch/series, stating beginning and end. When it comes to batches/series made up of several sets, they shall be identified.
e.- Operations and manufactures as stated in the application for registration of the product.
f.- Size of batch/series.
g.- Date of packaging and amount of packaging that the batch is made up of.
h.- Analytical and/or biological controls over each batch according to the patterns approved for each product and the results obtained.
i. Number of samples which shall be taken and patterns that shall be followed in accordance with the specific patterns that have been laid down according to the product type.
j.- Expiration date.
k.- Protocol number for series/batch and set.
l.- Signature of technician in charge.

Section 22

For the purposes of control, establishments shall keep the records and three representative samples of each batch in their original packaging for at least one year after the date its validity expires. For commercial packaging larger than a kilogram or a liter, the representative samples shall be of 100 g or 100 ml, respectively, and shall include all the data and indications of the original packaging.

ON THE REGISTRATION

Section 23

The registering body shall make a single request that the technician in charge provide further information where necessary. Such request shall be answered within a 45-day (forty-five) period. Non-compliance shall cause the proceeding to be filed.

Section 24

The issuance of registration certificates for products which shall meet requirements included in specific regulations and/or efficacy or efficiency tests shall be postponed until such requirements are met.

Section 25

The registration certificates that veterinary products are granted shall be valid for 10 years. The renewal thereof shall be requested up to 120 days before their expiration date.

I) When renewing the registration of a product whose features have been kept, submitting new information shall not be necessary unless progress in technical and scientific knowledge so requires.
II) The competent official body shall renew the registration certificates within a period longer than 30 days before expiration date where appropriate.

Section 26

The adoption of the same name for a veterinary product of different composition is prohibited even when manufactured by the same laboratory:

I) When making a change in a product formula which involves changing the active substance, the company owning the product registration with a certain name shall cancel such registration and use another name for the new product.
II) The use of the same brand may be authorized provided that the new product keeps the same therapeutic indications and the change in the formula is stated on the labels.

TRANSFER OF REGISTRATION TITLE

Section 27

The Registration Certificate of a Veterinary Product may be transferred to another establishment by the registration holder provided that the requirements laid down in the Regulatory Framework of Veterinary Products and in this regulation are complied with.

I) The new holder shall only market the product as of the time the registration certificate is granted.
II) The certificate period of validity shall be the same as the one of the original registration in force.

ON THE SAMPLES FOR VETERINARY PRODUCT CONTROL

Section 28

The collection of veterinary product samples for control shall conform to the specifications related to each product.

I) TERMS FOR SAMPLE COLLECTION

a) When collecting the sample, a Collection Record shall be prepared in 3 (three) copies, which shall be signed by an official staff member and the representative of the establishment owning the sample. The product nature, number of batch/series, date of manufacture and expiration in addition to other product features shall appear in the Record.

b) At least three identical samples shall be collected from each product. Such samples shall be wax-sealed separately and put into packages which shall be signed by an official staff member and the representative of the establishment in order to prevent violations. One of the samples shall be kept for counterevidence analysis by the product holder for the purposes of defense precisely along with the first copy of the Record. The other copies along with the original of the Record shall be sent to the official or accredited control laboratory to be analyzed by the staff member in charge of the collection.

c) When the representatives of the establishment refuse to sign the Record, such Record shall be signed by two witnesses without prejudice to the criminal proceedings that may arise therefrom.

d) In the event of a simultaneous collection of several products, the number of Records drawn up shall be the same as the number of products collected, complying with the formalities of this section.

e) An analysis certificate shall be made by the competent Official Body. Such certificate shall be given to the Establishment within a 5-working day period.

f) The company shall be formally notified of the analysis result. If such result is non-compliant, the company shall have a 10 (ten)-day period as from notification date to request the counterevidence analysis. Upon the expiration of such period and in the absence of any formal answer on the part of the company, the analysis result shall be considered final.

g) The expert's opinion about the counterevidence shall be issued with the sample kept by the company. The counterevidence analysis shall not be conducted should any signs of violation of the counterevidence exist.

h) The expert's opinion about the counterevidence shall be issued within a 30 (thirty)-day period as from the date of the company request. It shall be issued by a commission made up of the technician who carried out the previous test and another one appointed by the company and a third party chosen by the official body and the company. The result of the expert's opinion about the counterevidence shall be recorded in a report, the second copy of which shall be delivered to the company upon receipt. In case opinions differ in the result, a motion may be filed before the competent official body. The period to file a motion shall be of 10 (ten) days as from the time the analysis result is received. Such motion shall be answered within a 10 (ten)-day period.

II.- SAMPLE COLLECTION METHOD

The sample shall be collected in the original packaging which shall be sealed, unbroken, suitably prepared so as to prevent violations and kept under the storage conditions laid down on the label.

a) In the absence of specific rules, the sample shall be collected in triplicate from the lightest or smallest presentation available at the Establishment chosen.

b) Packaging
Each container shall be numbered, wax-sealed, sealed and signed by each of the acting parties. The product name, certificate and batch/serial number, expiration date, and sample collection date shall appear on the outside of the package. The acting parties shall also write their names.

**RZ 765/96 continued**

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IMPORTATION OF EXTRA-ZONE VETERINARY PRODUCTS

Section 29

In the application for registration of imported veterinary products, the following requirements shall be complied with:

I) Technical Application in accordance with the template approved for each product type signed by the legal representative and the technician in charge.

II) Authorization certificate of the manufacturing company of the country of origin.

III) Name of the legal representative of the establishment represented and document confirming such representation. By means of such document, s/he is

authorized and responsible for complying with the regulatory requirements, including violations and penalties, before the competent official body.

IV) Certificate of registration of the product and/or certificate of non-prescription in the country of origin.

V) Statement of the authority of the country of origin where indications for use (including the target animal species,) the product full formula and the product and Certificate of Registration period of validity shall appear.

VI) Name of the technician in charge of the representing establishment and the corresponding registration number in the professional Body where appropriate.

VII) For the imported veterinary product to be released, the interested party is bound to submit the Certificate of Registration of the product and the authorization of the registering body to the customs office. When it comes to biological products, they shall be accompanied by the quality control protocol.

VIII) The imported veterinary product not having a Certificate of Registration shall not be released by the customs office and shall remain at the disposal of the competent authority.

IX) The registrations granted to imported products shall be valid for up to 10 (ten) years as in their country of origin.

a) Should the registration of an imported product be canceled or suspended in its country of origin, the legal representative shall notify the registering official body of such a situation and justify it for the body to evaluate whether the local registration shall be kept or canceled.

Section 30

The following imported veterinary products shall be exempted from the Registration:

I) Products intended for official or private entities for the purposes of scientific research with prior authorization of the registering body.
II) The application for the import authorization submitted to the competent official body and referred to in the previous item shall include:
a) Name, features, indications for use, origin, provenance, and amount of the product to be imported.
b) Port of entry and estimated date of arrival of the material.
c) Body and technician in charge of research.
d) The experimental protocol shall include:
1) research goals and objectives
2) place where the experience shall take place
3) validation methods and criteria
4) implementation schedule

III) Any import of active substances and biological products in progress intended for manufacturing veterinary products registered with the competent official body shall be carried out by the owner and holder of the Registration of the finished product. Such information shall be recorded by means of data filing systems, specifying origin, number and destination.

ON THE MARKETING OF VETERINARY PRODUCTS

Section 31

The marketing of Veterinary Products, after registration by the competent Official Body, shall comply with the following classification:

I) Dispensed as an official non-repeat prescription;
II) Dispensed as a veterinary non-repeat prescription;
III) Dispensed as a veterinary prescription;
IV) Dispensed as a non-prescription product.

Section 32

The competent official body shall set specific rules for the criteria of active substance classification according to their therapeutic class allowing the products to fit within the aforementioned classification.

Section 33

The marketing of the products shall be conditioned upon the presentation of the final leaflets for them to be compared with the previously approved drafts.

Section 34

The marketing of veterinary products that have expired, as well as putting them up in new packaging or attaching new labels to them, is strictly prohibited.

ON FRAUDS, ALTERATIONS AND VIOLATIONS

Section 35

For the purposes of this regulation, the following are substances or products that have been altered, adulterated, counterfeited or are unfit for veterinary use:

I) Those mixed or packaged with other substances changing or reducing their therapeutic value.
II) Those whose compositions become different from the one stated in the registration because their formula elements have been withdrawn or replaced in whole or in part, or their compositions have foreign substances or elements of lower quality, or their concentrations have been changed.

III) Those whose purity, quality and/or number are different from the requirements which are stated herein and due to which they were registered.
IV) Those having changes in their labels, period of validity, date of manufacture or other elements which may be misleading.
V) Those whose pharmacopoeia volume, weight or unit do not match the registration-approved amount.

Section 36

The following are considered to be infringements subject to penalties as provided for herein and in the supplementary rules of each Member State:

I) Veterinary product labels, package leaflets or advertising that do not observe the provisions hereof and other relevant rules or contradict the conditions of the relevant registrations.
II) Alterations of the manufacturing process or the formulation without prior authorization of the competent body.
III) The product industrialization without the technician in charge being present.
IV) Refusal to provide information and documents or omission thereof when requested by the competent health authority.
V) The marketing of unregistered veterinary products.
VI) The marketing of veterinary products whose period of validity has expired or whose batch/serial number, date of manufacture, or expiration date are not stated.
VII) The marketing of veterinary products under conditions unsuitable for them to be properly preserved.

Section 37

Should the product alteration be attributable to its improper preservation or other storage conditions not related to the manufacturer's or legal representative's responsibility (when dealing with imported products,) provided that they are exempted from sales suspected of being fraudulent or being made in bad faith, such product sale shall be prohibited. The manufacturer or legal representative shall be bound to withdraw the product from the market and destroy it.

I) Should the fact that the distributor or seller is responsible for the alterations be confirmed, the Competent Official Body shall impose the relevant penalties on them.

ON THE SUPERVISION AND CONTROL OF VETERINARY PRODUCTS

Section 38

The supervising and controlling action shall cover each and every product dealt with herein: the manufacturing, importing, fractionating, storing and selling establishments and the vehicles intended for product transportation. Product

advertising and publicity through any media is also subject to the supervising and controlling action.

I) The supervising and controlling action is within the jurisdiction of the registering official body.

II) The officers in charge of supervision and control shall be vested with the following prerogatives:

a) They have free access to the places where industrialization, marketing, or transportation takes place.
b) They may collect the samples necessary for quality control.
c) They may be present during regular visits of supervision and control.
d) They may verify the origin and conditions of the products on sale.
e) They may verify that the workers who participate in manufacturing products comply with the health and personal hygiene conditions required.
f) They may suspend in whole or in part manufacture in the establishments referred to in Section 1 hereof and other relevant rules by drawing up the relevant record.
g) They may seize batches/series of products that are suspicious.
h) They may render products unusable where appropriate.
i) They may draw up Infringement Records to institute the relevant administrative proceedings.

III) The officers who are referred to herein and in the performance of their duties are bound to show their identifying card when requested to do so.

IV) Should cooperation were denied, or the action of the officers in charge of supervision and control were hampered, or their access to the premises where there may be finished veterinary products or where such products are manufactured, fractionated or marketed were blocked, officers shall ask the police to help for the purposes of ensuring the development of inspection, regardless of the penalties stated herein or in supplementary rules.

## CHAPTER VIII

## GENERAL PROVISIONS

### Section 39

The establishments registered shall inform the competent official body of any change made in the plant, facilities, technical management, formulation, and printed material of veterinary products registered.

### Section 40

The bibliographic references, scientific information, and experimental data submitted as a reference shall include:

a) name of author(s)
b) year and title of publication
c) volume, page, and other data identifying the research conducted by individuals or entities recognized by the accredited official body

l) Unpublished documentation shall only be accepted when the documentation owner's authorization is attached.

Section 41

The establishments manufacturing or importing biological products or pharmaceuticals under a specific control rule shall be bound to inform the competent official body of the batch/serial number, amount manufactured, date of manufacture, and validity of each batch before releasing such batches for consumption.

Section 42

The technical information submitted by the registering establishments, particularly the pieces of information dealing with methods of manufacture, analysis and other data considered to be confidential shall be under the custody of the registering authorities who shall ensure that such confidentiality is kept.

Section 43

The competent official body shall reject the registration of names proposed by the manufacturer when such names may lead to wrong conclusions about their composition, therapeutic indications, indications for use, method of administration and provenance.

l) The following shall not appear on labels or in advertising of veterinary products: designations, symbols, figures, designs or any indication which may lead to misinterpretations, errors or confusion regarding their origin, provenance, composition, quality or which may attribute to products purposes or features other than those they actually have.

Section 44

Upon the cancellation of a product registration, the owning establishment shall notify the following data regarding the last batch/series imported or manufactured within an 8-(eight)day period as from notification:

a. date of manufacture and expiration
b. batch number
c. product stock at the establishment

Section 45

The manufacturing establishments duly registered shall manufacture veterinary products exclusively intended for export in extra-zone countries with prior authorization of the competent official body by complying with the following requirements:

a. The production authorization shall be requested by the manufacturing establishment by means of an application for summary registration (formula, presentation and manufacturing precautions,) accompanied by a copy of the product certificate of registration in the country of destination.
b. The products manufactured within this framework shall not be marketed in the national territory and shall be exclusively intended for export.

Section 46

When a firm has had a product registered for it to be manufactured in the country and makes an official request to import the same product from another country, such firm shall be able to obtain the registration of the imported product without being bound to cancel or suspend the registration for local manufacture.

Section 47

Specific rules for production, control and use of veterinary products shall be laid down.

Section 48

Where necessary, to the discretion of the registering official body, the labels and package leaflets of veterinary products shall include information important to users or consumers in accordance with specific rules for each product type or category.

Section 49

The establishments currently authorized shall be bound to submit a plan of adaptation to this regulation within a period not longer than 180 (one hundred and eighty) days as from the internalization thereof. The adaptation period shall not be longer than 4 (four) years.